Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2255280	05/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Accurate Clinical Laboratory Corp	18800 Amar Rd, Ste C-11, Walnut, CA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on touring and observation of the laboratory facility and interview with the laboratory personnel, it was determined that that the laboratory failed to construct and provide the laboratory spaces to perform molecular amplification procedures that are not contained in closed systems having a unidirectional workflow, including separate areas for specimen preparation, amplification, and product detection, and, as applicable, reagent preparation. The findings included: a. The laboratory performed SARS-CoV-2 testing using Thermo Fisher ABI 7500 Real Time PCR instrument with Zeeson SARS-CoV-2 Test Kit (Real-time PCR). b. The laboratory failed to construct and provide separate areas for specimens receiving, process, reagent preparation, amplification and detection.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation and review of the laboratory's temperature records, review of

	the manufacture's insert for product storage temperature requirement on the package label, and interview with the laboratory staff, it was determined that the laboratory failed to follow the manufacturer's instruction and in a manner that provide test results with the laboratory stated performance specification for each test system. The findings included: a. The laboratory failed to follow the manufacture's instruction to store a control material in a temperature required under -70 oC. b. TaqPath COVID -19 Control, Positive Control for TaqPath, Lot #26003 expired on 2024-05-02 has been stored in a Whynter freezer which was set to - 20 oC.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification and validation records for SARS CoV-2 real time PCR, and interview with the laboratory staff, it was determined that the laboratory failed to validated the following performance characteristics: 1) Accuracy, 2) Precision, 3) Analytical sensitivity, 4) Analytical specificity, 5) Reportable range of test results for the test system, 6) Reference intervals (normal values), 7) Any other performance characteristic required for test performance. The findings included: a. The laboratory failed to perform validation of SARS-CoV-2 (Real time PCR testing procedure using nasal swap samples by using Thermo Fisher ABI 7500 Fast Dx PCR and the reagents manufactured by Xiamen Zeeson Biotech Co Ltd.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on touring and observation of the laboratory facility, review of the temperature records, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system and provide quality laboratory services. The findings included: a. The laboratory failed to construct and provide separate areas for SARS CoV-2 real-time PCR testing procedures, see D-3005 b. The laboratory failed to follow the manufacturer's instruction to store a control material in a required temperature setting, see D-5411 c. The laboratory failed to validate the SARS CoV-2 testing using Zeeson reagents for nasal specimens, see D-5423